REMARKS

The Response, filed in response to the Office Action mailed October 16, 2010, is believed to fully address all and every issue raised in the Office Action. Favorable reconsideration and allowance of application are respectfully requested.

Disposition of Claims

Claims 1-8 are all the claims pending in the application. Claims 1-8 have been considered and rejected.

No claim is amended.

Response to the Rejections under 35 U.S.C. §§ 102 and 103

Summary of Rejections

In the Office Action, claims 1-6 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Woo, US 6107290 in view of Deutsch, US 4897270, and Alavi, J. Pharmaceu. Sci.

In the Office Action, claim 7 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Woo, US 6107290 in view of Deutsch, US 4897270 and Alavi, J. Pharmaceu. Sci, and further in view of Murakami, US 3867414.

In the Office Action, claim 8 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Woo, US 6107290 in view of Deutsch, US 4897270, Alavi, J. Pharmaceu. Sci, and Murakami, US 3867414, and further in view of James, US 4865851.

Woo, US 6107290 ("Woo") is cited as teaching a non-crystalline cefuroxime axetil formulation for oral administration. According to the Examiner, Woo provides a non-crystalline (amorphous) dispersable solid form of cefuroxime axetil from a crystalline form of cefuroxime axetil by combination with a surfactant and a water insoluble inorganic carrier. The dispersant shows no absorption peak on a Differential Scanning Calorimetry scan (see claim 1 of Woo).

The Examiner admits that Woo is silent on the composition comprising a sucrose fatty acid ester and a methacrylic acid-ethylacrylate copolymer.

Deutsch, US 4897270 ("Deutsch") is cited as teaching that polymer systems based on methacrylic acid and esters thereof such as Eudragit are useful in the formulation of cefuroxime axetil with a disintegrant. Deutsch is silent on the use of sucrose fatty acid ester.

Alavi, J. Pharmaceu. Sci ("Alavi") is cited as teaching the combination of sucrose stearate (ScSt), as a droplet stabilizer in drug formulations, with Eudragit (methacrylic acid-ethylacrylate copolymers) to provide enteric coated microparticles.

According to the Examiner, it would have been prima facie obvious to one of ordinary skill in the art to combine the dispersible solid form of Woo with the methacrylic acid esters (Eudragit) taught in Deutsch and Alavi and the sucrose stearate taught by Alavi to provide a granule composition as in the instant claims.

Further, Murakami (US 3867414) is cited as teaching mix-melting an active ingredient with a nonionic surface active agent, cooling the melt mixture and then pulverizing the solid obtained either through colloid mill (abstract) or a mortar (example 3).

James, US 4865851 ("James") is cited as teaching a molten lipid dispersion of defuroxime axetil in the range of 60 to 80 degrees Celsius, preferably 65 to 70 degrees Celsius depending on the particular lipid material to be used. The Examiner asserts that the teaching of

James gives guidance as to the temperature required to disperse the defuroxime axetil into a fluid.

Applicants' Arguments

Applicants respectfully traverse for the following reasons.

1. Technical features of the subject invention

The subject invention defined in the claims of the subject invention relates to a cefuroxime axetil granule composition comprising a non-crystalline cefuroxime axetil solid dispersion or a substantially amorphous cefuroxime axetil, sucrose fatty ester, methacrylic acid-ethylacrylate copolymer and a disintergrating agent.

In this regard, the gist of the subject invention resides in the unique combination of the above components. By this technical feature, the subject cefuroxime axetil granules provide highly desirable performance characteristics in terms of masking the bitterness of cefuroxime axetil, as well as high bioavailability and stability of cefuroxime axetil, and, thus, can be advantageously used for oral administration of cefuroxime axetil.

2. Comparison of the subject invention with the cited references

The Examiner asserts that it would have been prima facie obvious to a person skilled in the art to combine the dispersible solid form of Woo with the methacrylic acid esters, i.e., Eudragit taught in Deutsch and Alavi and the sucrose stearate taught by Alavi to provide a granule composition as in the subject claims, since a person skilled in the art could have combined the elements of the prior art as claimed by known methods, and in combination each element merely performs the same function as it does in the prior art; further, all of the cited references are directed to improvements in drug formulation.

Applicants respectfully disagree.

Combination of Woo, Deutch, and Woo fail to teach all and every elements of claims.

The Examiner asserts that Deutsch taches that polymr systems based on methacrylic acid and esters thereof, such as Eudragit are useful in the formulation of cefuroxime axetil. Page 3, last full paragraph of the Office Action. However, the "Eudragit" taught in Deutsch is not a methacrylic acid-ethylacrylate copolymer recited in the claims of the instant application. Deutsch discloses that a cefuroxime axetil tablet core may be coated with a film-forming composition and a film-forming agent may be polymer systems based on methacylic acid and esters thereof such as Eudragit E and Eudragit E 30D. Eudragit E and E 30D disclosed in Deutsch are a cationic polymer which are different from methacrylic acid-ethylacrylate copolymer recited in the subject specification. To support this, Applicants submit a copy of Comparative Toxicogenomics Database regarding Eudragit E and E30D.[1] Therefore, Deutsch fails to disclose the use of methacrylic acid-ethacrylate in conjuction with cefuroxime axetil. Accordingly, the combination of Woo with Deutsch and Alavi would not result in the composition defined in claim 1. Furthermore, Deutsch fails to teach or suggest that methacrylic acid esters can be replaced by or modified to methacrylic acid-ethylacrylate copolymer, for the purpose of use in cefuroxime axetil formulation.

Therefore, the rejection of claims 1-6 based on the combination of Woo, Deusch, and Alavi cannot be sustained.

[1] Applicants believe that no Information Disclosure Statement is required for entry and consideration of the Comparative Toxicogenomics Database, because the reference is submitted solely to support Applicants arguments which are presented in response to the Examiner's Rejection. MPEP 609.05(c).

There is no motivation to combine Woo, Deutch, and Alavi to reach the claimed invention.

Furthermore, it is noted that Alavi is related to a formulation of enterosoluble microparticles for an acid labile protein. Cefuroxime axetil, which is the active ingredient of the subject invention, is totally different from a protein. Thus, Alavi merely discloses use of Eudragit L and S as an enteric coating material, but fails to teach the use of Eudragit L and S for cefuroxime axetil formulation. Further, Alavi discloses that sucrose stearate (ScSt) was used as a droplet stabilizer since it localized at the interface between the dispersed phase and the dispersion medium promoting dispersion and preventing flocculation. Alavi is silent on the problem of bitterness, bioavailability and stability of an active ingredient. Therefore, Alavi fails to teach use sucrose stearate for cefuroxime axetil formulation (as discussed above, the active ingredient in Alavi is an acid labile protein) and fails to provide any motivation to use sucrose stearate in cefuroxime axetil formulation (as Alavi does not mention whether sucrose stearate may be used to mask bitterness of an active ingredient; instead, Alavi uses sucrose stearate as a droplet stabilizer promoting dispersion and preventing flocculation in the process of preparation process of microparticle comprising an acid labile protein).

Consequently, the combination of the cefuroxime axetil composition recited in claims 1 to 6 cannot be readily derivable from Woo in view of Deutsch and Alavi. Moreover, the subject invention utilizing said unique combination of the cefuroxime axetil composition exhibits remarkably beneficial effects of less bitter taste, higher stability and higher bioavailability of cefuroxime axetil.

Neither of Murakami or James cure the deficiencies of Woo, Deutsch and Alavi.

Therefore, it is clear that the subject invention has distinguishably unique technical features and shows unexpectedly beneficial effects that cannot be derived from the cited references, even if they are combined. Accordingly, the subject invention defined in claims 1 to 6 is evidently patentable and unobvious over the cited references.

The same reason mentioned above can be applied to the inventiveness of claims 7 and 8 of the subject application. Moreover, Murakami and James neither disclose nor suggest the unique combination of the subject invention as mentioned above.

Accordingly, withdrawal of the rejections is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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